

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL NO: 05-4645

- - - - -
COLLEEN MARY GROBELNY and :
ROBERT GROBELNY, :
 :
Plaintiffs, :
 :
vs. : OPINION
 :
BAXTER HEALTHCARE CORPORATION :
and THE AMERICAN RED CROSS, :
 :
Defendants. :
- - - - -

Newark, New Jersey
Friday, August 3, 2007

B E F O R E:

HONORABLE PETER G. SHERIDAN, U.S.D.J.

A P P E A R A N C E S:

Pursuant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record taken stenographically in the above entitled proceedings.

S/IRA N. RUBENSTEIN, C.S.R.
Official Court Reporter

IRA N. RUBENSTEIN, CSR, Official Reporter, Newark, N.J.

1 THE COURT: Plaintiff Grobelny filed this action
2 against Baxter Healthcare Corp., American Red Cross and Robert
3 Wood Johnson Hospital.

4 Following Grobelny's adverse reaction to medical
5 treatment by a prescribed intravenous immunoglobulin infusion.
6 More specifically, while hospitalized at Robert Wood Johnson
7 prior to surgery to remove her spleen, plaintiff received an
8 IVIG infusion on February 7, 2002 as prescribed by Doctor Fang.
9 The IVIG was prescribed to increase the platelets count. IVIG
10 is an abbreviation for intravenous immunoglobulin as is
11 administered in advance of surgery. It's used in the treatment
12 of immunodeficiency disorders. See Dorland Illustrated Medical
13 Dictionary 1999 at 778.

14 Gamagard S/D and Polygam S/D manufactured by Baxter,
15 are immunoglobulin products that are regulated by the FDA. Such
16 product can only be prescribed by a physician. Within the
17 Gamagard and Polygam package there is a package insert which is
18 identical in both products. The packaging purports to identify
19 possible side effects precautions and warnings. It has a
20 subsection entitled "precaution," under the word "precaution,"
21 it has another heading entitled "general." Within the "general"
22 section it states "there is clinical evidence of a possible
23 association between immunoglobulin, intravenous immunoglobulin
24 IVIG administration and thrombotic events. The exact cause of
25 this is unknown. Therefore, caution should be exercised in the

IRA N. RUBENSTEIN, CSR, Official Reporter, Newark, N.J.

1 prescribing and confusion of IVIG in patients with a history of
2 cardiovascular disease or thrombotic episodes."

3 Defendants assert the packaging received FDA approval
4 and, in opposition, plaintiff states no documents attesting to
5 the fact of such approval have been submitted to the Court or
6 provided to plaintiff during the course of discovery.

7 Following the IVIG therapy, Plaintiff, who claims to
8 have no history of cardiovascular disease or thrombotic
9 episodes, suffered a renal vein thrombosis. A thrombotic event
10 is the formation of a blood clot in a blood vessel, artery or
11 vein.

12 Despite plaintiff's claim she had no history of
13 cardiovascular disease and thrombotic episode, plaintiff was
14 treated by Doctor Fang for thrombocytopenia beginning March 2001
15 and was treated for idiopathic thrombocytopenia purpura
16 throughout 2001.

17 Moreover, defendants maintain the medical records
18 reveal that plaintiff may have issues antiphospholipid syndrome
19 a condition in which antiphospholipid anti-body increase the
20 tendency of blood to clot spontaneously.

21 Defendants offered an affidavit of a Doctor Shiff which
22 provides that thrombotic events are commonly associated with
23 antiphospholipid syndrome. And said association is commonly
24 well-known in the medical community and recognized by scientific
25 research.

1 Before this Court is whether the warnings were
2 sufficient, N.J.S.A. 2A:58C-4. The statute states, "In any
3 product liability action the manufacturer or seller shall not be
4 liable for harm caused by a failure to warn if the product
5 contains an adequate warning or instruction...if the
6 manufacturer or seller provides an adequate warning or
7 instruction. An adequate product warning or instruction is one
8 that a reasonably prudent person in the same or similar
9 circumstances would have provided with respect to the danger and
10 that communicates adequate information on the dangers and safe
11 use of the product, taking into account the characteristics of,
12 and the ordinary knowledge common to, the persons by whom the
13 product is intended to be used, or in the case of prescription
14 drugs, taking into account the characteristics of, and the
15 ordinary knowledge common to, the prescribing physician. If the
16 warning or instruction given in connection with the drug or
17 device...has been approved or prescribed by the Federal Food and
18 Drug Administration under the [Statute] a rebuttable presumption
19 shall arise that the warning or instruction is adequate."

20 The statute while limiting liability when an adequate
21 warning is used, leaves open a state law claim for liability
22 under failure to warn if the plaintiff can establish that the
23 warning provided by the manufacturer was "not an adequate
24 product warning or instruction" under the statute.

25 Although 2A:58(c)4 offers an avenue to pursue a failure

1 to warn claim, New Jersey courts have limited the availability
2 of such a claim when the warnings that have been FDA approved.
3 The Supreme Court has found that federal regulations serves as
4 compelling evidence that a manufacturer satisfied its duty to
5 warn the physician about a potential harmful side effect of the
6 product. See *Perez v. Wyeth* at 161 N.J. 1 at 24 (1999). The
7 Court stated:

8 "The legislature determined that FDA approval of a
9 drug's safety and labeling a significant factor...which created
10 a prima facie defense to any claim against the manufacturer
11 based upon allegedly insufficient warnings. By creating a
12 rebuttable presumption the legislature provided a strong but not
13 absolute defense, declining to immunize drug manufacturers and
14 allowing a plaintiff who could present sufficient evidence of an
15 inadequate or incomplete warning to prevail." *Rowe versus*
16 *Hoffman-LaRoche*, 383 NJ Super 342, (App. Div.) rev'd on other
17 grounds 189 New Jersey 615 (2007).

18 Plaintiffs argues that defendants have failed to
19 provide any documentation supporting the assertion that the FDA
20 approved the processing distribution and packaging inserts of
21 Gamagrad and Polygam. Thus, defendants are not entitled to
22 rebuttal presumption under the statute. Previously, the Court
23 ordered the defendants to produce the relevant documents
24 regarding the approval of the Gamagard and Polygam warning
25 labels.

IRA N. RUBENSTEIN, CSR, Official Reporter, Newark, N.J.

1 With regard to the FDA approval, the Court has reviewed
2 the defendants submission. The submission has numerous letters
3 and correspondence and regarding telephone conferences with the
4 FDA. However, nowhere in the document does there appear to be a
5 clear approval of the package insert and the warning on those
6 products. So, under the circumstances here, there's no
7 presumption of an adequate warning.

8 In general, it's the manufacturers duty to warn the
9 consumer and this duty is not necessarily satisfied by
10 compliance with the FDA's minimal warning requirements; thus
11 warnings must not be misleading, and must be adequate to explain
12 to the user possible dangers associated with the product.
13 Whether the duty has been satisfied is governed by state common
14 law which necessarily implicates a fact finding process. Am. L.
15 Prod Liab., 3d, Section 33:37.

16 In this case the packaging clearly speaks to the,
17 "possible association between Immune Globulin Intravenous
18 (Human) (IGIV) administration and the thrombotic events." The
19 second sentence limits the caution to patients with a history of
20 cardiovascular disease or thrombotic episodes. So based upon
21 the non-approval of the FDA the motion for summary judgment on
22 behalf of the defendant is denied.

23 However, a question of fact arises sufficient at least
24 on this motion for summary judgment, to rebut the presumption,
25 as to whether there was sufficient clinical evidence to support

1 further warning of thrombotic events beyond patients with a
2 history of cardiovascular disease or thrombotic episode. As
3 result the motion for summary judgment is denied.

4 (Matter adjourned.)

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

IRA N. RUBENSTEIN, CSR, Official Reporter, Newark, N.J.

